SAT Report

PMN Number: **P-12-0437**
SAT Date: **7/17/2012**
Print Date: **11/26/2014**

Related cases: [redacted]

Concern levels:

Type of Concern:	Health	Eco	Comments
Level of Concern:	1-2	2	

Persistence	Bioaccum	Toxicity	Comments
2	1	1 Awaiting Human Health Entry Awaiting Human Health Entry Awaiting Human Health Entry	

Exposure Based Review:

Health: Yes
Ecotox: Yes

Routes of exposure:

Health: Dermal Inhalation
Ecotox: All releases to water
Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: P-12-0437 [redacted]

FATE:

[redacted]

VP < 1.0E-6 torr at 25 C (E)

BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 50-90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = mo
Sorption to soils/sediments = strong
PBT Potential: P2B1
*CEB FATE: Migration to ground water = slow

Health:

Health Summary: Absorption is nil all routes based on physical/chemical properties. This material may be irritating to the skin and eyes. There is concern for lung effects if respirable particles are inhaled based on changes in the [redacted] balance in the lungs and/or cationic binding to lung tissues. Low moderate concern.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	**96-h**	**LC50**	2.0		
daphnid	**48-h**	**LC50**	2.1		
green algal	**96-h**	**EC50**	2.0		
fish	**_**	**chronic value**	0.11		
daphnid	**_**	**chronic value**	0.15		
algal	**_**	**chronic value**	0.50		
Sewage Sludge	**3-h**	**EC50**	**_**		
Sewage Sludge	**_**	**Chronic Value**	**_**		

Ecotox Values Comments:

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb)	11	
SARs	[redacted]	
SAR Class	[redacted]	
Ecotox Category		

Ecotox Factors Comments:

SAT Chair: Becky Jones

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Focus Report

New Chemicals Program

PMN Number: **P-12-0437**

Focus Date:	07/30/2012	Report Status:	Completed
Consolidated Set:			
Focus Chair:	Darlene Jones	Contractor:	Stephen Wieroniey

I. Notice Information

Submitter: [redacted]

CAS Number: [redacted]

Chemical Name: [redacted]

Use: [redacted]

Other Uses: [redacted]

PV-Max: [redacted]

Manufacture:

Import: X

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 2 **Comments:** ;

Occupational: 2-3D **Non-Occupational:** **Environmental:** 3

(1) **PBT:** 2 1 1 **Comments:**

III. OTHER FACTORS

Categories:

Health Chemical Category:

Ecotox Category: [redacted]

Related Cases/Regulatory History:

Health related Cases: [redacted] (SAME COMPOUND)

Ecotox Related Cases: Analogs: [redacted].

Regulatory History: [redacted] CCD DISPOSITION DROP-EXPOSURE BASED
-WITHDRAWN/FACE 5E
-FOCUS DROP

MSDS/Label Information:

MSDS: Yes Label: No

General Equipment: Hand protection: The suitability for a specific workplace should be discussed with the producers of the protective gloves. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough. // Eye protection: Eye wash bottle with pure water. Safety glasses. Wear face-shield and protective suit for abnormal processing problems. // Skin and body protection: Choose body protection according to the amount and concentration of the dangerous substance at the work place. Wear as appropriate:. Protective suit. Safety shoes.

Respirator: Wear a supplied-air NIOSH approved respirator unless ventilation or other engineering controls are adequate to maintain minimal oxygen content of 19.5% by volume under normal atmospheric pressure. Wear a NIOSH approved respirator that provides protection when working with this material if exposure to harmful levels of airborne material may occur, such as:. Dust safety masks are recommended when the dust concentration is excessive. Use a positive pressure, air-supplying respirator if there is potential for uncontrolled release, exposure levels are not known, or other circumstances where air-purifying respirators may not provide adequate protection.

Health Effects: Causes skin irritation. // Causes serious eye irritation.

TLV/PEL (PMN or raw material): - None established.

Exposure Based Information:

Exposure Based Review:	Y	Exposure Based Review (Health):	Y
Exposure Based Review (Eco):	Y	Exposure Based (Occupational):	No
Exposure Based Review (Non Occupatuional):	N	Exposure Based (Environmental):	

Exposure Parameter	Exposure-Based	Persistent/Bioaccum	Exposure Value
Surface DW:	Yes	Yes	
Fish Ingestion:			
Ground DW:			
Inhalation:			
Water Releases:			
Total Releases:	Yes		
Consumer Exposure:	Yes		

IV. Summary of SAT Assessment

Fate:

Fate Summary:

P-12-0437
FATE:

S = Dispersible (E)
VP < 1.0E-6 torr at 25 C (E)
BP > 400 C (E)
H < 1.00E-8 (E)
POTW removal (%) = 50-90 via sorption and biodeg
Time for complete ultimate aerobic biodeg = mo
Sorption to soils/sediments = strong
PBT Potential: P2B1
*CEB FATE: Migration to ground water = slow

Health:

Health Summary:

Absorption is nil all routes based on physical/chemical properties. This material may be irritating to the skin and eyes. There is concern for lung effects if respirable particles are inhaled based on changes in the balance in the lungs and/or binding to lung tissues. Low moderate concern.

Ecotox:

Ecotox Values:

Fish 96-h LC50:	2.0(P)
Daphnid 48-h LC50:	2.1(P)
Green algal 96-h EC50:	2.0(P)
Fish Chronic Value:	0.11(P)
Daphnid ChV:	0.15(P)
Algal ChV:	0.50(P)

Ecotox values comments:

Predictions are based on SARs for ; SAR chemical class = ; S = dispersible in water at 20 C (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L;

Ecotoxicity Test Data Results for P-12-0437:

An acute marine copepod toxicity study was conducted on PMN P-12-0437 The study was completed in 2012 by Opus Plus Limited The PMN is characterized as a that is dispersible in water. The study was conducted according to 'ISO 14669 (1999) Water Quality -Determination of acute lethal toxicity to marine copepods (Copepoda; Crustacea)'; GLP compliance was not stated.

A 48-hour marine copepod acute toxicity study was conducted with the PMN under static testing conditions. Following a range-finding study, two replicates of ten Acartia tonsa per concentration were exposed to nominal concentrations of 0 (dilution water control), 1, 3.2, 10, 32, or 100 mg/L. Based on statements made in the study report, the definitive test was conducted twice since irregular results were observed in the first definitive test; however, detailed results were only presented for one of the tests. Methods for preparing test solutions were described as a water accommodated fraction (WAFs), which was considered acceptable since the PMN appears to be a mixture. However, since the submitter prepared a single stock solution that was subsequently diluted to achieve desired nominal test concentrations, the submitter did not follow methods for preparing WAFs (OECD guidelines, ASTM guidelines) that require individual preparation of each test concentration. Thus, the submitter's technique for test solution preparation was considered unacceptable. In addition, no attempt was made to quantify the amount of PMN in solution compared to controls (e.g., TOC analysis). Test organisms were 19 days old at test initiation. Over the course of the study dissolved oxygen concentrations of 89-98%, pH levels of 8.05-8.16, and water temperatures of 20.7-21.5 °C were reported. Dilution water hardness was not provided. Percentage mortality was 0%, 9%, 0%, 20%, and 90% in the 0, 1, 3.2, 10, 32, and 100 mg/L exposure groups for the initial definitive test. In the second definitive test, 25% and 85% mortality was observed at nominal concentrations of 10 and 18 mg/L, respectively. The submitter provides a nominal 48-hour LC50 of 21.7 mg/L, which appears to be based on the initial definitive test that was considered by the submitter to have irregular results. Based on interpolation of the provided results for the follow-up definitive test, the 48-hour LC50 would be about 13 mg/L. Since the inadequate method for preparing WAFs may have resulted in lower concentrations than what was reported, the LC50 was considered to be ≤13 mg/L. The study was considered unacceptable based on the absence of test concentration analysis to confirm amount of substance achieved in each test concentration and the inadequate approach for preparing test solutions.
48-hr LC50 ≤ 13 mg/L

The submitted study was considered unacceptable. Predictions based on the [redacted] QSAR will be used to determine risk are also no effects at saturation for all aquatic acute and chronic endpoints. The 96-hour fish LC50 was 2 mg/L, the 48-hour daphnid LC50 was 2.1, the 96-hour algae EC50 was 2 mg/L, the fish ChV was 0.11 mg/L, the daphnid ChV was 0.15 mg/L, and the green algae ChV was 0.5 mg/L. An acute CoC of 400 ppb was calculated based on the fish 96-hour LC50 (2 mg/L) divided by an assessment factor of 5. A chronic CoC of 11 ppb was calculated based on the fish ChV (0.11 mg/L) divided by an assessment factor of 10.

Acute CoC = 400
Chronic CoC = 11

Ecotox Study Reviewer: K. Moran QA/QC: L. Newsome 7/19/2012

Ecotox Factors:

Assessment Factor: 10
Concern Concentration: 11

V. Summary of Exposures/Releases

Engineering Summary: P-12-0437

Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Output 2	Output 2	Output 2
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Release
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Output 2	Output 2	Output 2
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers			
Exposure Type			

V. Summary of Exposures/Releases

Engineering Summary: P-12-0437

Exposures/Releases	Release	Exposure	Exposure
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	Output 2	High End	Upper Bound
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers		[redacted]	[redacted]
Exposure Type		[redacted]	[redacted]

Engineering Summary: Exposures/Releases	Exposure	Exposure	Exposure
Scenario	[redacted]	[redacted]	[redacted]
Sites	[redacted]	[redacted]	[redacted]
Media	[redacted]	[redacted]	[redacted]
Descriptor A	High End	Upper Bound	High End
Quantity A (kg/site/day)	[redacted]	[redacted]	[redacted]
Frequency A (day/year)	[redacted]	[redacted]	[redacted]
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]	[redacted]	[redacted]
Workers	[redacted]	[redacted]	[redacted]
Exposure Type	[redacted]	[redacted]	[redacted]

V. Summary of Exposures/Releases

Engineering Summary: P-12-0437

Exposures/Releases	**Exposure**		
Scenario	[redacted]		
Sites	[redacted]		
Media	[redacted]		
Descriptor A	Upper Bound		
Quantity A (kg/site/day)	[redacted]		
Frequency A (day/year)	[redacted]		
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	[redacted]		
Workers			
Exposure Type	[redacted]		

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: PMN Ban Pending Upfront Testing Decision Date: 07/30/2012
Type of Decision:

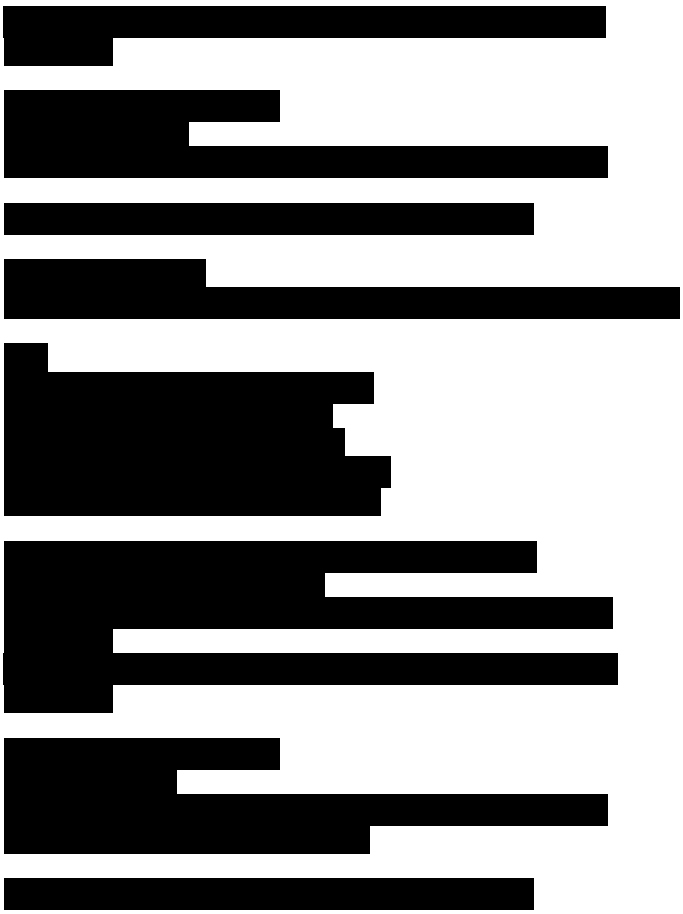
Rationale: P-12-0437 will be regulated under the TSCA 5(e) category [redacted] Ban Pending Upfront Testing under the risk based authority for ecotoxicity concerns and the exposure based authority for human health, fate and ecotoxicity concerns. Human health hazard concerns were low-moderate for inhalation and dermal exposures. In the action letter the submitter will be asked to update the MSDS to include 'adverse effects to lungs', 'tight fitting goggles', 'impervious gloves' and a 'NIOSH-certified particulate respirator'. The human health testing will be a 90 inhalation toxicity test (OPPTS guidelines 870.3465 in rats with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and to various parameters of the bronchoalveolar lavage fluid (BALF) with a 60-day holding period. Ecotoxicity hazard concerns were moderate based on EcoSARs predictions for [redacted]. Potential acute risk to the environment were high based on releases to water in which the SWC of [redacted] and exceeded the acute COC of 400 ppb during processing operations. Potential chronic risk the to environment were high based on releases to water which exceeded the chronic COC of 11 ppb 108[redacted] release days [redacted] during use operations. The required risk-based ecotoxicity testing will consist of the acute base set: Algal toxicity, Tiers I and II (OPPTS Test Guidelines 850.5400), Aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guidelines 850.1010), and Fish acute toxicity test (OPPTS Test Guidelines 850.1075) and fish acute toxicity mitigated with humic acid (OPPTS Test Guidelines 850.1085). Fate testing is the Activated sludge sorption isotherm test (OPPTS 835.1110) with attention given to the use of a specific analytical method capable of quantifying the PMN substance in the activated sludge aqueous matrix. If the submitter feels that biodegradation may be an important removal process the Zahn -Wellens/EPMA test (OPPTS 835.3200), Modified SCAS Test (OPPTS 835.3210 or the Porous pot test (OPPTS 835.3220) could be conducted instead of the Activated sludge sorption isotherm test. The following CEB exposure based criteria were met: # of workers exposed [redacted] The associated sustainable futures case is [redacted] which was denied at focus.

COC: Chronic – 11 ppb; Acute – 400 ppb

Summary of Exposures and Releases:

[redacted]

[redacted]



P2 Rec Comments:

Testing:

Prefocus Recommended:

Health: Inhalation only

Final Recommended:

Health:

Eco:

Fate:

Other:

Briefing Paper

Case Number: **P-12-0437**

Part I: Background Data

Program Manager: Jesse Miller
Review Team:
Meeting Date:
Day 90: 10/19/2012

Technical Integrator:

Day In Process: 87

A. CBI Claims:
B. Submitter: [redacted]
C. Chemical Identity: [redacted]
D. Chemical Class:
Ecotox [redacted]

E. Structure:

[redacted]

F. Physical/Chemical properties:

VP: Measured Torr @ 25 C
Est. <0.000001 Torr @ 25 C
s-H2O: Measured g/L
MW: [redacted]
Phys State: Neat: [redacted]
Manufacturing: NK: Import
Process/Form: [redacted]
End Use: [redacted]

G. Volume: [redacted]
H. Use:

I. Test Data Submitted:
J. MSDS:

MSDS: Yes Label: No
General equipment: Hand protection: The suitability for a specific workplace should be discussed with the

producers of the protective gloves. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough. // Eye protection: Eye wash bottle with pure water. Safety glasses. Wear face-shield and protective suit for abnormal processing problems. // Skin and body protection: Choose body protection according to the amount and concentration of the dangerous substance at the work place. Wear as appropriate:. Protective suit. Safety shoes.

Respirator: Wear a supplied-air NIOSH approved respirator unless ventilation or other engineering controls are adequate to maintain minimal oxygen content of 19.5% by volume under normal atmospheric pressure. Wear a NIOSH approved respirator that provides protection when working with this material if exposure to harmful levels of airborne material may occur, such as:. Dust safety masks are recommended when the dust concentration is excessive. Use a positive pressure, air-supplying respirator if there is potential for uncontrolled release, exposure levels are not known, or other circumstances where air-purifying respirators may not provide adequate protection.

Health Effects: Causes skin irritation. // Causes serious eye irritation.

K. SAT Ratings:

Human Health: 1-2 ; Environment: 2 ;

L. Focus Results: P-12-0437 will be regulated under the TSCA 5(e) category [redacted] Ban Pending Upfront Testing under the risk based authority for ecotoxicity concerns and the exposure based authority for human health, fate and ecotoxicity concerns. Human health hazard concerns were low-moderate for inhalation and dermal exposures. In the action letter the submitter will be asked to update the MSDS to include 'adverse effects to lungs', 'tight fitting goggles', 'impervious gloves' and a 'NIOSH-certified particulate respirator'. The human health testing will be a 90 inhalation toxicity test (OPPTS guidelines 870.3465 in rats with special attention to histopathology (inflammation and cell proliferation) of the lung tissues and to various parameters of the bronchoalveolar lavage fluid (BALF) with a 60-day holding period. Ecotoxicity hazard concerns were moderate based on EcoSARs predictions for cationic surfactants. Potential acute risk to the environment were high based on releases to water in which the SWC of [redacted] and exceeded the acute COC of 400 ppb during processing operations. Potential chronic risk the to environment were high based on releases to water which exceeded the chronic COC of 11 ppb 108[redacted] release days [redacted] during use operations. The required risk-based ecotoxicity testing will consist of the acute base set: Algal toxicity, Tiers I and II (OPPTS Test Guidelines 850.5400), Aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guidelines 850.1010), and Fish acute toxicity test (OPPTS Test Guidelines 850.1075) and fish acute toxicity mitigated with humic acid (OPPTS Test Guidelines 850.1085). Fate testing is the Activated sludge sorption isotherm test (OPPTS 835.1110) with attention given to the use of a specific analytical method capable of quantifying the PMN substance in the activated sludge aqueous matrix. If the submitter feels that biodegradation may be an important removal process the Zahn -Wellens/EPMA test (OPPTS 835.3200), Modified SCAS Test (OPPTS 835.3210 or the Porous pot test (OPPTS 835.3220) could be conducted instead of the Activated sludge sorption isotherm test. The following CEB exposure based criteria were met: [redacted] The associated sustainable futures case is [redacted] which was denied at focus.

COC: Chronic – 11 ppb; Acute – 400 ppb

Summary of Exposures and Releases:

[redacted]

[redacted]

[redacted]

Part II: New Information

The submitter clarified that the physical state of the PMN material is a [redacted] This eliminated the releases and exposures due to [redacted]. There are no longer any releases to water and the CEB exposure based criteria are no longer met.

Part III: Recommendation and Rationale

The exposure based criteria are no longer met and the eco-tox risk was mitigated due to no releases to water. The PM recommends to Drop the case with a non-5(e) SNUR.

The conditions of the SNUR would be:

1. Use as stated in the PMN
2. water trigger of 11 ppb
3. recommended testing would be those stated in the Focus Results above

Part IV: Risk Summary

A. Health Effects:

Absorption is nil all routes based on physical/chemical properties. This material may be irritating to the skin and eyes. There is concern for lung effects if respirable particles are inhaled based on changes in the [redacted] balance in the lungs and/or [redacted] to lung tissues. Low moderate concern.

B. Environmental Effects:

Ecotox: predicted (P) and measured (M) toxicity value is mg/L (ppm) are:

Fish 96-h LC50:	2.0(P)
Daphnid 48-h LC50:	2.1(P)
Green algal 96-h EC50:	2.0(P)
Fish Chronic Value:	0.11(P)
Daphnid ChV:	0.15(P)
Algal ChV:	0.50(P)

C. Environmental Releases and Exposures:

D. Risk Estimates:

Part V: Exposure Criteria Met

Exposure Based Review (Chemistry):	● Yes ○ No	**Exposure Based Review (Health):**	● Yes ○ No
Exposure Based Review (Ecotox):	● Yes ○ No	**Exposure Based Review (Occupational):**	● Yes ○ No
Exposure Based Review (Non-Occupational):	○ Yes ● No	**Exposure Based Review (Environmental):**	○ Yes ○ No

Exposure Based Review Criteria--Engineering Report		Amt
1. Number of Workers Exposed > 1000?	[redacted]	[redacted]
2. > 100 Workers With > 10 mg/Day Inhalation Exposure	[redacted]	
3a. > 100 Workers With 1-10 mg/Day Inhalation Exposure >100 Days/Yr	[redacted]	
3b. > 250 Workers With Routine Dermal Contact > 100 Days/Yr	[redacted]	

Exposure Parameter	Exposure-Based	Persistent/Bioaccum	Exposure Value
Total Releases:	● Yes ○ No	○ Yes ○ No	[redacted]

Part VI: Tests

Final Testing Recommendation
Health:
Eco:
Fate:
Other:

Comments:

Part VII: Other Factors

A. Substitutes:

B. Benefits:

C. Other Uses: [redacted]

D. Other:

Part VIII: Regulatory History

[redacted]3-CCD DISPOSITION DROP-EXPOSURE BASED
[redacted]WITHDRAWN/FACE 5E
[redacted]-FOCUS DROP

Comments:

Last Updated by

Document Created by Jesse Miller on 10/18/2012